Remarks/Argument

REMARKS

In the Office Action dated February 13th, 2004, claims 1-29 of the present invention were rejected under 35 U.S.C. 103(a) as being unpatentable over Mansour (4,693,9972). As there are only 25 claims in the present invention, the Rejection's reference to claims 1-29 is believed to be mistaken. After carefully studying the Office Action and making amendments to the application, the applicant respectfully requests favorable reconsideration.

The Rejection states that Mansour teaches that fluorescence microscopy has been utilized to selectively stain bacteria in blood samples. But, the method taught by Mansour discloses the use of ethidium bromide as a stain, which is not membrane-permeable and does not stain live bacteria, unlike the stain used in the present method. Describing Mansour's method in the last paragraph of page 1, the applicant explains that Mansour's "sample preparation requires an extra step of permeablizing the bacterial cell membrane without disrupting the cell if detection of bacterial contamination is desired." The presently claimed invention eliminates this step by utilizing membrane-permeable nucleic acid stains. Nothing in Mansour suggests the use of membrane-permeable nucleic acid stains to stain bacteria in platelets.

Another distinction between the method as taught in Mansour and the method presently claimed is the use of digital image acquisition technology. Mansour's method for counting microorganism cells discloses the use of cytometers which are expensive and labor intensive to use. The use of digital image acquisition technology is not taught or suggested by Mansour.

Mansour states in column 2 that, "there is a need for a better method for the rapid detection of microorganisms in body fluid samples." The present invention attepmts to solve these problems. The use of membrane-permeant nucleic acid stains ultimately saves time by eliminating the need to permeablize the bacterial cell membrane and the use of digital image acquisition technology allows for greater precision, being able to detect concentrations as low as 3.10×10^3 CFU/ml. Applicants respectfully submit that

the current improvements were not obvious to one of ordinary skill in the art, as evidenced by the long-felt need to solve the problems.

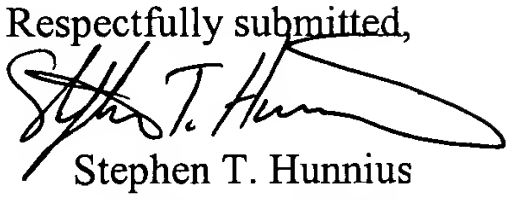
The Rejection states that no criticality is seen in the degree of lysis claimed or the concentrations of the reagents. This rejection is respectfully traversed. Concerning the degree of lysis, on the 7th page, third paragraph of the present application, applicant explains how if enough red blood cells or platelets are not lysed the membrane filter will become plugged. The applicant further explains how the fluorescence emitted by unlysed platelets could interfere significantly with the measurement results. The degree of lysis claimed is therefore critical to the present invention. The degree of lysis achieved is controlled by the amount of reagent utilized. The applicant discloses on page 6, paragraphs 6 and 7 the amount of lytic agent required for the present method to be effective. The concentrations of reagents are therefore critical to the method as claimed.

Claims 2-29 (again, believed to be referring to claims 2-25) were rejected under 35 U.S.C. § 112 for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The applicant has amended the claims in accordance with section 112. All dependent claims now begin with a definite article. In claim 3 and 23, "destroying" has been replaced with "lysing" as supported by paragraph 3 of page 7 of the specification. All trademark names in the claims have been replaced with generic terminology. The Abstract of the Disclosure has been limited to one paragraph to comply with M.P.E.P. § 608.01(b). No new matter has been added by this amendment.

In conclusion, reconsideration and withdrawal of the rejections based on 35 U.S.C. §§ 103 and 112 are respectfully urged. Favorable reconsideration and allowance at the Examiner's earliest convenience are earnestly requested.

Kindly charge any additional fees due, including the fee for an extension of time, or credit overpayment of fees, to Deposit Account No. 50-0281.

Respectfully submitted,



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